Chairman and
Chief Executive Officer

One Baxter Parkway
Deerfield, Illinois 60015
847.948.3600

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June 12, 1997

The Honorable Donna E. Shalala
Secretary of U. S. Department of
Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I have been following with great concern the petition of CellPro, Inc. requesting that the Department of Health and Human Services exercise "march-in" rights under the Bayh-Dole Act. I have also followed, with dismay, CellPro's public relations campaign to persuade cancer victims and their families that unless DHHS exercises "march-in" rights, patients will no longer have access to stem cell technology. Baxter will not allow patient care to be compromised. If CellPro reduces support for any clinical site, we will take steps to assure that there will be no gap in patient access to this important technology.

Today Baxter and VIMRx Pharmaceuticals Inc. are announcing a strategic alliance which we believe will expand and enhance our participation in the cell therapy business. I want to avoid any misinterpretation of this announcement and would like to elaborate on our actions to maintain all of our commitments to patients.

Under the provisions of a letter of intent that has just been signed, Baxter and VIMRx intend to form a new company that combines the ex vivo cell selection and storage business of Baxter's Immunotherapy Division with VIMRx's access to genomics technology in an innovative structure to create a leading comprehensive ex vivo cell and gene therapies enterprise. It is expected that this transaction will be completed in the third quarter of 1997.

We are excited about the opportunity the VIMRx alliance will provide for us to expand the number of patients who can benefit from cellular therapies. This alliance enhances Baxter's commitment to, and involvement in, the support of patients needing stem cell selection as part of their cancer therapy.

Baxter will retain the responsibility and the ability to support the clinical and research needs for stem cells for transplant. Specifically, in this transaction:

- Baxter maintains ownership of its exclusive license for the use of Johns Hopkins' patented CD34 technology in therapeutic applications and will provide the alliance company with a sublicense.

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- Baxter will continue to manufacture the Isolex® devices and associated disposables for the alliance company.

- Baxter will be the exclusive worldwide sales, marketing, and distribution agent for the alliance company for the Isolex® 300 System in support of stem cell selection for the treatment of cancer.

As you may know, Baxter's Isolex® 300 System is approved for sale in Europe and is used extensively at U.S. transplant centers in clinical trials addressing both autologous and allogeneic transplantation for treatment of breast cancer, lymphoma, multiple myeloma, leukemia (including mismatched donor transplants), autoimmune diseases and genetic diseases. It is my understanding that our system is being used in as many U.S. clinical sites as CellPro's system, and that at least half the sites use both systems. Based on published clinical trial data, we believe that our system is equivalent or superior to CellPro's system for the selection of stem cells and depletion of tumor cells.

Baxter's pending PMA application for FDA approval is now going through active review by the FDA. In May, the FDA completed the first of two clinical site visits; the second is scheduled for next week. Late last week, we were notified that our PMA submission is being considered for presentation to an FDA advisory committee in late July. We believe the PMA is on track for approval by the end of this year.

I understand that CellPro has suggested in recent filings with NIH that if the federal court were to grant equitable relief to plaintiffs, CellPro might reduce its support of clinical sites using the CellPro system. I am troubled that a company devoted to patient care would make these threats and create unnecessary anxieties on the part of cancer patients.

I directed our legal counsel in the ongoing patent litigation with CellPro to take steps to ensure that any injunctive relief entered by the federal court would permit CellPro's continued sale of its Ceprate® SC products, and its continued provision of those products to clinicians involved in clinical trials, pending FDA approval of a medically equivalent alternative. However, I want to confirm that if CellPro reduces support of any clinical site that does not already have Baxter's Isolex® 300 System available as an alternative, Baxter will install its device at the CellPro site free of charge and will provide that site the same support CellPro was providing on the same contract terms. We will also provide all necessary clinical, regulatory, and technical support to put the Baxter system into operation as quickly as possible.

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This is a commitment of Baxter and will be unaffected by the creation of the alliance with VIMRx. We trust that this commitment, together with the other steps we have taken, will assure you that there will be no gap in patient access to stem cell technology as a result of any order the federal court may enter.

Finally, I want to emphasize my deep concern that the initiation of a "march-in" proceeding in this case would do great damage to the considerable good that has been accomplished by the Bayh-Dole Act since its enactment in 1980. The Act has made it possible for companies like Baxter to invest substantial resources in medical research and innovation within our nation's universities and hospitals. The critical assumption, however, is that when we obtain an exclusive license under patents covering government-supported inventions, these patent rights will be respected, and our investment in product development, clinical trial support, regulatory filings and the many other costs of bringing a product to market will be protected.

If DHHS were to initiate a "march-in" proceeding on behalf of a willful infringer of patented technology, where an authorized licensee in good faith invested tens of millions of dollars to obtain an exclusive license and commercialize patented medical technology, it is hard to see why any company would be willing in the future to invest in government-supported medical research. This would have a tragic impact on the development of innovative treatments for cancer and other diseases.

In closing, I want to reiterate that Baxter will not allow patient care to be compromised. Baxter's business is based on providing patients and physicians with life-saving technologies. It is a heritage of which we are very proud and which will continue as long as Baxter has products, technologies and services to offer.

Sincerely,

VRL:kjs

cc: Harold Varmus, M.D.